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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/977,787	11/25/1997	LEE MIZZEN	STS96-02A	3496

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EXAMINER	
CLOW, LORI A	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 06/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 08/977,787	Applicant(s) MIZZEN ET AL.	
	Examiner Lori A. Clow, Ph.D.	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *53,56-58,60-68 and 87-123* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *53,56-58,60-68 and 87-123* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 36 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows: The application of which applicant claims benefit, 08/756,621 (now abandoned) does not disclose in the specification a fusion protein wherin the CTL epitope is a class-I restricted T-cell epitope. Nor does the specification disclose a fusion protein wherein the CTL epitope is a class II-resrticted T-cell epitope. Furthermore, there is no disclosure of a fusion protein wherein the HPV antigen is present or that the HPV fusion protein is used to prevent or treat HPV infection.

> *The second application must be an application for a patent for an invention which is also disclosed in the first application (the parent or provisional application); the disclosure of the invention in the parent application and in the second application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See Transco Products, Inc. v. Performance Contracting, Inc., 38 F.3d 551, 32 USPQ 2d 1077 (Fed. Cir. 1994).*

Applicants' arguments, filed 8 March 2002, have been fully considered by they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims Rejections-35 USC 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 53, 56, 60-68, and 87-95, are rejected under 35 U.S.C. 102(b) as being anticipated by Young (US 6,338,952). Young discloses compositions comprising a stress protein joined to another component, such as a fusion protein in which a stress protein is fused to an antigen (abstract). Specifically, Young teaches that the stress protein along with an antigen are fused (column 11, lines 58-63) and that the stress protein may be fused to a wide variety of antigens, including bacterial, viral, parasitic, or other antigens (column 9, lines 62-67), which would meet all of the limitations included in claim 53. Furthermore, claim 56 is anticipated by column 12, lines 8-24 which expressly lay out that the antigens may come from any substance against which an immune response is desired, including Influenza virus, which would encompass the antigens set forth in claim 56. The fusion protein is capable of inducing an immune response against the antigen in a mammal to whom the fusion protein is administered, as in claim 60 and as disclosed specifically in column 12, lines 11-12. Furthermore, the fusion protein contains a bacterial stress protein from mycobacterium (column 5, line 52) as required by claim 61.

A composition comprising a fusion protein of claim 53 and a pharmaceutically acceptable carrier is anticipated by Young in column 13, lines 8-9 and lines 66-67. Furthermore, the fusion protein of claim 53 is capable of inducing an immune response that is cell mediated response, as

in column 12, lines 7-10 and one which is cytolytic in nature, as in column 7, lines 35-42 and column 10, lines 65-67, thus meeting the limitations of claims 62-68.

Young also teaches the fusion protein of claims 87-97 in that he discloses in column 12, lines 64-67, the strong and specific B and T cell mediated immunity that can be generated in a mammal by administering the fusion protein of choice. T cell responses include those that are CD 4^+ and CD 8^+, thus encompassing a CTL response that is both class I and class II mediated/restricted. Since the fusion protein can include ANY antigen claims 89 and 90 are also taught by Young. Furthermore, Young specifically teaches the use of stress proteins hsp65 and hsp71, or any stress protein for that matter, as stated in column 10, lines 33-39).

Claims Rejections-35 USC 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Applicant's arguments with respect to 35 USC 103 have been considered but are not deemed persuasive. Applicant claims that fusion proteins containing stress proteins are known in the art but that this does not mean that all fusion proteins containing stress proteins are obvious. However, Young (in US 6,338,952) specifically points out that the stress protein may be conjugated to ANY substance against which an immune response is desired or to a portion of the substance sufficient to induce an immune response in an individual to whom it is administered. The substance can include but is not limited to protiens (e.g., ovalbumin, INFLUENZA VIRUS HEMAGGLUTININ, HIV p24), peptides (e.g. HIV peptides, melanoma antigen peptides), oligosaccharides (e.g. *Neiserria meningitides* group B, *Streptococcus pneumonia* type 14, *Hemophilis influenzae* type B), lipids, carbohydrates (e.g., glycolipid antigens in human cancers such as GD3, GM2, Gb3, Forssman antigen, Sialosyl-Le^a antigen and glycoprotein antigens in human cancers such as CEA, AFP, PSA, Tn antigen), organic molecules or a combination thereof (column 12, lines 10-24).

Claims 57, 58 are rejected under 35 USC 103 as being unpatentable over Young (US 633,952).

Young teaches the subcloning of the HIV p24 gag gene into the stress protein fusion vector pKS70 to produce the pKS72 vector (column 12, lines 40-47) and further states that a stress protein could be conjugated to ANY antigen, thus meeting the limitations of claims 57 and 58. While the plasmid vectors are not the same, it would have been prima facie obvious to one of ordinary skill in the art to have modified the methods of Young, using a favorable or comparable plasmid vector suitable to facilitate the particular antigen of interest and this could be done with a reasonable expectation of success.

Further, claims 98-123 are rejected under 35 USC 103 as being unpatentable over Young (US 633,952) in view of Srivastava (US 6,030,618). As shown above, Young teaches all of the embodiments requiring the fusion proteins of claims 98-123. However, Young does not specifically mention HPV as an antigen. Srivastava does teach the use of HPV as a potential antigen to use in a fusion protein that is conjugated with a heat shock protein (column 7, line 52). Furthermore, this invention is directed specifically at treating or preventing an infectious disease (such as HPV) or cancer (column 5, lines 15-18), as required by claims 120-123. Thus it would have been prima facie obvious for one of ordinary skill in the art to have modified the invention of Young and Srivastava to design and implement hsp-fusion proteins with HPV. Young provides the motivation in that it is clear that he teaches that ANY antigen could be fused to ANY hsp in order to elicit a specific, cell-mediated immune response as required by all embodiments of the instant application.

Claims 89-123 are also rejected under 35 USC 103 as being unpatentable over Young and in further view of Lathe et al. (US 6,007,806), for the reasons set forth in the previous office action.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

All claims are rejected.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242, or (703) 308-4028.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (703) 306-5439. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Patent Analyst, Bill Phillips, whose telephone number is (703) 305-3419, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

May 31, 2002

Lori A. Clow, Ph.D.
Art Unit 1631

MICHAEL P. WOODWARD
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600